DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

MCMR-RCQ (70-1n)

12 August 2003

HSRRB Policy Memorandum 2002-08, Version 02

SUBJECT: Medical Care for Research-Related Injury

1. REFERENCES.

a. 32 Code of Federal Regulations (CFR) 219, *Protection of Human Subjects*

b. DOD Directive 3216.2, *Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research*, 25 March 2002

c. AR 40-400, *Patient Administration*, 12 March 2001

d. AR 70-25, *Use of Volunteers as Subjects of Research*, 25 January 1990

e. OTSG 15-2, *Human Subjects Research Review Board*, 11 January 1989

2. HISTORY. This is the second version of HSRRB Policy Memorandum 2002-08. This version is effective 23 Oct 03. Details of the history can be found in Appendix A.

3. PURPOSE. This policy clarifies the requirements for medical care for subjects with research-related injuries.

4. SCOPE. This policy applies to protocols submitted for review by The Surgeon General's Human Subjects Research Review Board (HSRRB).

5. REGULATORY BACKGROUND.

a. Federal regulations governing human subjects medical research (The Common Rule) require that research subjects involved in greater than minimal risk research must be informed of the availability of medical treatment or compensation if a research-related injury occurs. This information should inform the subject if treatment is available, and if it is, what that consists of or where further information may be obtained (32 CFR 219.116). This regulation does not require the Principal Investigator (PI) or the research sponsor to provide treatment.

b. Department of Defense Directive 3216.2, March 25, 2002 affirms Army and

OTSG policy that extended medical protections for research subjects beyond the Common Rule requirements. DODD 3216.2 requires the DoD components to protect research subjects from medical expenses not otherwise provided or reimbursed that are the direct result of participation in a research project involving greater than minimal risk. This issue is addressed in DODD 3216.2, paragraph 5.3.4 as follows, requiring that the Heads of DoD Components shall:

> "With respect to research for which primary involvement is from the Department of Defense, establish the required administrative procedures to protect human subjects from medical expenses (not otherwise provided or reimbursed) that are the direct result of participation in a research project involving more than minimal risk. For this purpose the determination of primary involvement shall be based on consideration of the DoD portion of the total involvement (i.e., funding, personnel, facilities, and all other resources) in the research."

As stated in DODD 3216.2, paragraph 2.2, this directive "applies to research involving human subjects, as defined herein, conducted by a DoD Component (i.e., intramural) and other research that is supported by a DoD Component (i.e., extramural) through a contract, grant, cooperative agreement, or other arrangement."

c. The applicable Army Regulation, AR 70-25 at paragraph 3-1k, authorizes medical care for research subjects in Army medical treatment facilities (MTFs). It also specifically authorizes contracting officers to negotiate costs of medical care coverage or medical care direct charges for extramural research conducted via contract or grant, but does not mandate that extramural researchers provide this coverage. Paragraph 3-56 of AR 40-400, an Army medical care regulation, reiterates the availability of MTF-based care for injuries to research subjects arising from the medical research. Neither regulation limits access to medical care to subjects participating in greater than minimal risk research protocols.

d. OTSG Regulation 15-2 at appendix B1j. requires all USAMRMC-sponsored research protocols to include a clause in the consent form informing the subject that they are authorized all necessary medical care for research-related injuries and that contractors must provide for such medical care when working with civilian research subjects. This language does not address responsibility for the cost of care. It also imposes a medical care obligation on contractors that goes beyond the Common Rule and may be inconsistent with a contractor's policy.

6. POLICY. Research subjects participating in research protocols, regardless of level of risk, should be protected from research-related medical expenses by the Army to the extent possible. The cost of care for injuries may be billed to the research subjects' medical insurance in the ordinary manner. For extramural research, the Government

shall not be responsible to pay for medical care for such injuries when they are the direct result of the negligent or criminal act(s) of the contractor or grantee or their agents.

a. Intramural research.

(1) Subjects who are DoD healthcare beneficiaries (e.g., active duty military) are entitled to medical care for research-related injuries, to the same extent that such medical care would be provided if the injuries were not research-related. If any medical expenses for research-related injuries are incurred that are not covered within the DoD healthcare system, the intramural research institution will contact the U. S. Army Medical Research and Materiel Command and Fort Detrick (USAMRMC&FD) Office of the Staff Judge Advocate at (301) 619-7663/2221 to assist the research subject in pursuing reimbursement for research-related medical expenses (not otherwise provided or reimbursed). Reimbursement is not guaranteed.

(2) Subjects who are not otherwise eligible beneficiaries of the DoD healthcare system are nevertheless eligible for medical care for research-related injuries in Army MTFs under AR 40-400, 3-56 and Appendix B.

(a) If a subject is injured, the subject should be able to receive medical care at an Army MTF by presenting proof that he/she is seeking care for an injury that is a result of his/her participation in an Army research study. Sufficient proof for an Army MTF should consist of a memorandum signed by the Principal Investigator that (1) states that the individual is or was a subject in an Army research protocol who is seeking treatment for an injury that was a result of the subject's participation in the research; (2) clearly specifies the nature of the injury; (3) references AR 40-400, 3-56 ("**3–56. Volunteer subjects in approved Department of the Army research projects.** Volunteers ... are authorized necessary medical care for injury or disease that is the proximate result of their participation in clinical investigation or research protocols. Medical care charges for all categories of personnel described in this chapter will be waived when they require care which is the proximate result of participation in clinical investigation or research protocols") and (4) identifies the PI, and provides a telephone number where the PI can be reached. Alternatively, if a given Army MTF is reluctant to accept such proof, PIs or laboratory commanders can seek Secretarial Designation of eligibility for care in an Army MTF for any subject with research-related injuries, under AR 40-400, 3-50.

(b) If Army MTFs are unable to provide sufficient care, or the nearest MTF is not located within a reasonable distance of the subject (or it is otherwise unreasonable to require the subject to travel to the MTF), the intramural research institution will, or the research subject may, contact the USAMRMC&FD Office of the Staff Judge Advocate at

(301) 619-7663/2221 to assist the research subject in pursuing reimbursement for research-related medical expenses (not otherwise provided or reimbursed). Reimbursement is not guaranteed.

(c) If the subject needs emergency care for research-related injuries, the subject should obtain such care wherever appropriate, and contact (or have the research institution contact) the USAMRMC&FD Office of the Staff Judge Advocate to pursue reimbursement as soon as possible after receiving this care, as described above. Reimbursement is not guaranteed.

b. Extramural research.

(1) The contractor or grantee must have a policy consistent with the Common Rule. This merely requires the contractor or grantee to inform the subject if medical care or compensation is available for research-related injuries. Research subjects will receive medical care or compensation to the extent provided by the contractor or grantee. Subjects may be required by the contractor or grantee to use their own health insurance or health care provider. In addition, the research subject may seek care in an Army MTF for research-related injuries in accordance with AR 70-25 and AR 40-400.

(2) If the research subject incurs any research-related medical expenses (not otherwise provided or reimbursed) and the extramural research institution does not reimburse the subject, the research subject may contact the USAMRMC&FD Office of the Staff Judge Advocate at (301) 619-7663/2221 to assist the research subject in pursuing reimbursement for those research-related medical expenses. Reimbursement is not guaranteed.

c. Informed consent language.

(1) There is no specific, required language for informed consent forms. Informed consent forms must (a) inform subjects if they will receive medical care for research-related injuries; (b) inform subjects if they will receive compensation for their injury in addition to any medical care provided; (c) inform subjects if care for such injuries will be billed to their insurance company or to subjects; (d) inform subjects that they are not giving up any legal rights; (e) provide any other information that a subject would want to know about medical care for research-related injury; and (f) provide a point of contact for questions about such medical care or related expenses.

(2) The following language must be included in informed consent forms for extramural research, after the contractor's or grantee's language that explains the contractor's or grantee's policy on medical care for research-related injuries:

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"If you are hurt or get sick because of this research study, you can receive medical care at an Army hospital or clinic free of charge. You will only be treated for injuries that are directly caused by the research study. The Army will not pay for your transportation to and from the hospital or clinic. If you have questions about this medical care, talk to the principal investigator for this study, (name and telephone number of principal investigator). If you pay out-of-pocket for medical care elsewhere for injuries caused by this research study, contact the principal investigator. If the issue cannot be resolved, contact the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of the Staff Judge Advocate (legal office) at (301) 619-7663/2221."

Encl

Laura R. Brosch
LAURA R. BROSCH
COL, AN
Acting Chair, Human Subjects
Research Review Board

RECOMMEND APPROVAL/~~DISAPPROVAL~~

DATE: 190ct03
LESTER MARTINEZ-LOPEZ
Major General, MC
Chair, Human Subjects
Research Review Board

~~APPROVED~~/DISAPPROVED

FOR THE SURGEON GENERAL:

DATE: 23 Oct 03
KENNETH L. FARMER, JR., M.D.
Major General
Deputy Surgeon General

APPENDIX A

HSRRB Policy Memorandum History

Version Number: 02

Version Date: 12 August 2003

Effective Date: 23 Oct 03

Reason for Revisions: Initial version implied that government reimbursement of uncovered medical expenses would be guaranteed (it cannot), and imposed obligations on contractors and grantees that they are generally unable to meet..

Detailed List of Changes:

1. Minor non-substantive changes (e.g., date, Version number, effective date, signature blocks).
2. Changes paragraph 5d. to clarify interpretation of OTSG 15-2, and to eliminate reference to subordinate USAMRMC regulation.
3. Changes paragraphs 6 and 6a. to clarify that reimbursement of medical expenses is not guaranteed.
4. Changes paragraph 6b. to modify obligations placed on contractors and grantees regarding provision of medical care.
5. Changes paragraph 6c., informed consent language, to include language that must be incorporated into consent forms for extramural research.